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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

GUID. 609PA

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on May 17, 2006Signature Mark A. HollingsworthTyped or printed name Mark A. Hollingsworth

Application Number

10/801,139

Filed

March 15, 2004

First Named Inventor

Haefner

Art Unit

3762

Examiner

Kahelin, m.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 38,491

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Mark A. Hollingsworth
Signature

Mark A. Hollingsworth
Typed or printed name

952-854-2700
Telephone number

May 17, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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SERIAL NO. 10/801,139

PATENT APPLICATION

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	HAEFNER	Examiner:	Kahelin, M.
Serial No.:	10/801,139	Group Art Unit:	3762
Filed:	March 15, 2004	Docket No.:	GUID.609PA (03-527)
Title:	IMPLANTABLE DEVICE WITH CARDIAC EVENT AUDIO PLAYBACK		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this communication is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 17, 2006.

By 
Mark A. Hollingsworth

**APPELLANT'S STATEMENT IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented by Appellant in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant is requesting a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and are without basis. Appellant's request is based upon a clear legal or factual deficiency in the rejections, rather than an interpretation of the claims or the prior art teachings. As such, Appellant believes this request for pre-appeal brief review is proper.

Claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39 and 44 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,867,163 to *Schaldach* (hereinafter "*Schaldach*"). Claims 17, 19-21, 41, 45 and 46 stand rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over *Schaldach*. Claims 4 and 36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Schaldach* in view of U.S. Patent No. 6,477,406 to *Turcott* (hereinafter "*Turcott*"). Claims 8, 11 and 40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Schaldach* in view of U.S. Patent No. 5,935,081 to *Kadhiresan* (hereinafter "*Kadhiresan*"). Claims 14, 18, 22-24, 31, 33, 34, 43 and 47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Schaldach* in view of U.S. Patent No. 5,321,618 to *Gessman* (hereinafter "*Gessman*"). Claims 15, 26-29, 42 and 48 stand rejected

under 35 U.S.C. §103(a) as being unpatentable over *Schaldach* in view of U.S. Publication No. 2002/0026223 to *Riff* (hereinafter “*Riff*”).

The issues on appeal concerns whether each and every element of Appellant’s claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39 and 44 is found expressly or inherently in *Schaldach*. With regard to the obviousness rejections of the remaining claims, Appellant believes the asserted combinations of references, each of which includes *Schaldach* as the primary reference, fail to render these claims obvious, in view of the factually erroneous characterization of the *Schaldach* teachings. The central issue on appeal, therefore, is whether the Examiner’s characterization of the *Schaldach* teachings are factually deficient, and therefore whether the anticipation and obviousness rejections that rely on *Schaldach* are legally without basis.

Appellant has asserted, and hereby reasserts, that the Examiner has not identified where in *Schaldach* each and every feature of Appellant’s independent claims 1, 17, 32, and 44 is disclosed, either expressly or inherently. On page 2 of the Advisory Action dated May 4, 2006, the Examiner identifies portions of *Schaldach* that purportedly teach Appellant’s recited features. Respectfully, Appellant’s careful review of these and other portions of *Schaldach* reveals that the Examiner’s characterization of the *Schaldach* teachings are factually deficient.

In the Advisory Action, the Examiner contends that *Schaldach* discloses that various combinations of ‘characteristic fields’ are displayed on an external device (col. 23, line 59). The Examiner further contends that these ‘characteristic fields’ are input variables (col. 23, line 39). Appellant notes that Figure 6a of *Schaldach* that is discussed in column 23 is described, at column 7, lines 7-10, as a characteristic graph for *explaining* different variants of the exemplary embodiment. *Schaldach* further teaches, at column 23, lines 20-23, that Figure 6a provides an example for relationships, *stored in memories* having a matrix organization, between variables such as are used in the described pacemaker concept.

The Examiner further contends that *Schaldach* teaches that signals from sound pickups (col. 7, line 61) and cardiac electrical activity (col. 8, line 1) are input variables (col. 7, lines 31-68). Lastly, the Examiner contends that *Schaldach* discloses displaying the rate of cardiac electrical depolarizations versus presphygmic period, which is picked up by acoustic receivers (col. 27, line 26). Based on these teachings of *Schaldach*, the Examiner concludes that *Schaldach*’s invention clearly displays audio and cardiac electrical activity on a patient external device.

In addition to other features, each of Appellant's independent claims 1, 17, 32, and 44 recites communicating both a cardiac electrical signal and an audio signal representative of a cardiac non-electrophysiologic activity (e.g., heart movement) to a patient-external location. Although the Examiner argues that *Schaldach* teaches production of an audio signal by measured value pickups 117-120, the Examiner has not identified where in *Schaldach* there is a teaching or suggestion of telemetering such an "audio signal" to a patient-external location, along with a cardiac electrical signal. Appellant argued the absence of this feature in the prior responsive communications, which required the Examiner to particularly point out where this teaching in *Schaldach* is purportedly found. The Examiner has not provided such identification in the final Office Action or in the Advisory Action.

Appellant's careful review of *Schaldach* reveals no teaching or suggestion in *Schaldach* that any audio signal or other signal containing audio signal information is telemetered to a patient-external device along with a cardiac electrical signal. The reason for this absence of teaching appears clear, given the use of the signals derived from the measured value pickups 117-120 in *Schaldach*. As was strenuously argued in Appellant's prior responsive communication, the signals derived from the measured value pickups 117-120 are used to control pacing, including pacing rate. In particular, *Schaldach*, at column 20, lines 67-68, describes that the pressure or sound pickups measure stroke volume which is used in controlling pacing, including pacing rate.

Any audio signals derived from the measured value pickups 117-120 are used to control pacing, and are not described as being of interest beyond the context of pacing control. There is simply no teaching or suggestion by *Schaldach* that an audio signal is communicated outside the body by the disclosed device. *Schaldach* only teaches that a microphone may be used to derive measured values such as stroke volume, but does not teach that an audio signal of the type contemplated in Appellant's claims is produced from the microphone, or that any such audio signal is stored and/or communicated to a patient-external device.

Respectfully, the rejection of independent claims 1, 17, 32, and 44 under 35 U.S.C. §102(b) is not sustainable, as the Examiner has not established *prima facie* anticipation of each and every element recited in these claims. The disclosure in an anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the

subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). See, also, MPEP § 2121.01. Moreover, an objective reading of *Schaldach* clearly reveals that the identical invention as is recited in Appellant's claims is not "shown in as complete detail as is contained in the ... claim," which is a requirement for establishing *prima facie* anticipation. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Further, M.P.E.P. §2131 states that various portions of a reference cannot be asserted together to anticipate a claim unless the reference arranges the limitations as they are arranged in the claim. *Schaldach* clearly fails to teach an arrangement of its features that would render Appellant's independent claims 1, 17, 32, and 44 anticipated.

Appellant respectfully asserts that *Schaldach*'s description of a rate-adaptive pacemaker that uses sound pickups to derive measured value pickup signals for the stated purpose of controlling pacing or pacing rate is insufficient to support the Examiner's anticipation rejection of Appellant's claims 1, 17, 32, and 44. It is unclear how one skilled in the art could arrive at Appellant's claimed structure and functionality using *Schaldach*'s rate-adaptive pacemaker teachings without undue experimentation, particularly in the clear absence of a teaching regarding telemetering of an audio signal or other signal containing audio signal information to a patient-external device along with a cardiac electrical signal.

Concerning the Examiner's comments regarding claims 2 and 35 on page 3 of the Office Action, Appellant maintains its prior position that the accelerometer signal disclosed in *Schaldach* is used to detect patient activity. There is no teaching in *Schaldach* that the accelerometer signals in *Schaldach* that indicate patient motion are of sufficient frequency to constitute audible signals perceivable by the human ear. The Examiner's contention that the acceleration signals generated by patient movement in *Schaldach* meet Appellant's recitation of audio signals produced by the accelerometer recited in claims 2 and 35 is unsupported speculation. With regard to the Examiner's comments regarding claims 17, 30, and 38 on pages 3 and 4 of the Office Action, Appellant makes reference to the previously made remarks of the prior responsive communications and the remarks presented hereinabove.

Schaldach does not teach or suggest all of the claim limitations of Appellant's independent claims 1, 17, 32, and 44, and, therefore, these claims are not anticipated by

Schaldach. Dependent claims 2, 3, 5-7, 9, 10, 12, 16, 19-21, 35, and 37-39, which depend from independent claims 1, 17, and 32, respectively, are also not anticipated by *Schaldach*.

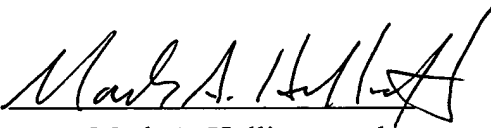
Concerning the various rejections of dependent claims under 35 U.S.C. §103(a) summarized above, each of these dependent claims depends from independent claim 1, 17, 32, or 44. For the reasons set forth above and in Appellant's prior responsive communications, independent claims 1, 17, 32, and 44 are not rendered obvious in view of *Schaldach*, alone or in combination with the other asserted references. For example, the asserted references fail to teach or suggest all limitations of Appellant's independent claims. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Appellant believes that this statement, when viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections of record are clearly not proper and are without basis.

The undersigned is of record and with authority to prosecute the appeal on behalf of the Assignee.

Respectfully submitted,

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